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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,004	12/04/2001	Dwight W. Miller	11613.7USC1	8268
45074	7590	12/10/2004	EXAMINER	
NATIONAL INSTITUTES OF HEALTH P. O. BOX 2903 MINNEAPOLIS, MN 55402			SODERQUIST, ARLEN	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,004

Applicant(s)

MILLER ET AL.

Examiner

Arlen Soderquist

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 11-30 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 and 24-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-18, 23-25 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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1. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 25 it is not clear how the food product is intended to provide a further limitation since it does not appear to be positively claimed as part of the food package nor is there any disclosure that the packaging materials would change based on the food that is packaged therein.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 13-14, 17-18 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Myerson (US 5,501,836). In the patent Myerson teaches a sensor made of porous matrix or sol-gel glass and non-enzymatic macromolecular polymer immobilized in the sol-gel glass. The macromolecule is physically entangled or otherwise trapped, and does not leach regardless of exposure to elevated temperature and pressure. Surface effects are minimized since there is no chemical bond between macromolecules and sol-gel glass. Indicator molecules may be attached to the macromolecular polymer either before or after the macromolecule is incorporated into the porous matrix. Columns 1-2 discuss problems with a variety of prior sensors due to leaching of the indicator. Column 4, lines 41-60 teach the sensor element is comprised of a sol-gel glass that has incorporated amongst or within its internal porous matrix an immobilized component, at least one type of nonenzymatic macromolecule to which an indicator is attached. The non-enzymatic macromolecule may be made from a variety of materials, however, the best results have been achieved with polyvinyl amine, polyallylamine, polyacrylic acid, and polyvinyl alcohol (all polymeric resins). Sol-gels suitable for the invention include a variety of inorganic silica sol-gel glass precursors, including tetra-alkoxysilanes. Extended pH stability can be obtained by forming the sol-gels of other precursor compositions, leading to products such as zirconia or titania. The non-enzymatic macromolecule is integrated into the porous matrix by being physically immobilized in the sol-gel by being entangled or otherwise firmly fixed to the sol-gel, whether entrapped in the pores or otherwise. In example 1, section A teaches the

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preparation of a phenol red-polyallylamine adduct (phenol red is a sulfonated hydroxy-functional triphenylmethane dye). Section B teaches the incorporation of this adduct into a sol-gel glass by preparing a stock solution using 4.92 ml of tetramethoxysilane (TMOS), 1.13 ml of water and 0.073 ml of 0.04 molar HCl (acid catalyzed polymerization as in the examples of the instant specification). This mixture is sonicated for 20 minutes, after which it becomes one-phase. Two (2) ml of the sol-gel stock solution, 2 ml of pH 6 phosphate, and 1 ml of solution containing the phenol red-polyallylamine adduct is mixed together and poured into a plastic petri dish. After gelation, the gel is cured for several (3-4) days, and then slowly dried over one week, the resulting slab of sol-gel glass shows the expected sensitivity: Under basic conditions, it is purplish-red and under acidic conditions it is yellow. Sections C and D teach a second method of arriving at the indicator being trapped within the sol-gel glass.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-6, 11-18, 23-25 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfbeis (US 5,407,829) in view of Attar (US 4,840,919), Balderson (US 5,439,648), Kanakkanatt (US 5,501,945), Mallow (US 5,183,763) and Myerson as explained above. In the patent Wolfbeis teaches a device for quality control of packaged substances in which figure 1 shows a substrate (4) having thereon an indicator layer (11) covered by a hydrophobic gas-permeable polymer film. Figure 2 shows a similar structure except the indicator is part of an emulsion with a gas-permeable, hydrophobic polymer film. The examples

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given correspond to the emulsion of figure 2. Relevant to the instant claims is the use of a polysilicone made by polymerization of a monomer (SiliconBasis PE 1055A) and the formation of an indicator sensitive to ammonia and amines (second example). Column 3, lines 7-19 teach that this provides the necessary selectivity to the gaseous substances or vapors. Column 2, lines 35-51 teach the use of **optical sensors** to measure the increase or decrease of one or more constituents within the package environment. Column 3 lines 32-40 teach the incorporation of reference areas to help in determining changes in color. Wolfbeis is silent on if the indicator layer (11) of figure 1 is a polymer matrix and does not teach the full extent of indicators or polymers or multiple sensing areas having different ratios of the indicator.

In the patent Attar teaches a device for detecting amines using 1,2-naphthoquinone-4-sulfonic acid. The device has a base (12, substrate) and an indicating layer (22) containing granular alumina or silica to assist with the detection of the amines. This is covered with a porous layer that is intended to reduce the effects of wind and moisture and a gas impermeable layer (14).

In the patent Balderson teaches the inclusion of multiple sensing areas in a packaged product to provide information on the change in one or more of the constituents in the packaged environment. This was done to provide information on relative changes in the packaged environment and overcome problems with prior art devices.

In the patent, several methods of using dyes within polymers, specifically in food packaging materials, are disclosed by Kanakkanatt. These dyes respond to specific stimuli and indicate exposure to stimuli by a change or shift in the frequencies of light they absorb. The stimuli include chemicals (e.g. H₂O, CO₂, NO₂, ethylene, and SO₂). Within packaging materials (or affixed thereto as a label, decal, or tag), these dyes could indicate spoilage or the possibility of spoilage, that the product has been irradiated, or that the product has been exposed to an undesirably high or low temperature. Many of the shifts in absorption frequencies result in visible color changes which a consumer could quickly identify. Thus, plastic chips molded from polystyrene and 6-nitro-1',3',3'-trimethylbenzoinindolinospiropyran turned purple on exposure to UV light, and then yellow on exposure to NO₂. The yellow chips turned red on immersion in hot water, or orange-red on exposure to NH₃.

In the patent Mallow teaches a paint or coating composition and method for detecting vapor or liquid reactants, such as ammonia. The composition is composed of ethyl cellulose as a binder or polymeric matrix, a filler, such as amorphous silica (silicic acid, diatomaceous silica, pyrogenic silica, biogenic silica or silica gel), and a dye, such as bromophenol blue. The composition serves as a passive detector for vapor or liquid reactants when applied to selected surfaces as a paint. The composition is capable of detecting extremely low concentrations of vapor. Further, the composition is capable of regenerating to its original color, thereby providing repeated detection capability. The substrate is the material to which the paint or coating is applied. The pH adjusting acid or alkali material, such as nitric acid, may also be varied depending upon the indicator selected. For example, acetic acid may be used as a pH adjustor for methylene red. The ethyl cellulose provides a desired combination of a water insoluble binder and a highly permeable membrane to let the detected gases, such as ammonia vapor, through. That is, ethyl cellulose provides a desired vehicle for transfer of vapor to the indicator and a binder for attaching the indicator to a wide variety of substrate materials, such as minerals, metals and papers. It is believed that the increased reagent sensitivity provided by the composition is obtained as a result of the presence of amorphous silica, which orients the dye and enhances the dye's response to reagents. That is, the amorphous silica absorbs the dye on its surface and helps to orient it in the composition film so that a higher number of dye molecules are available per unit of area or volume for response to the reagent. The amorphous silica therefore serves as a pigment, filler, substrate for dye, and sensitizer in the composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the dye of Wolfbeis into materials as taught by Myerson and use the dyes of Attar, Kanakkanatt, Mallow or Myerson as the indicator of Wolfbeis because of their known sensitivity to ammonia and amines as taught by Attar, Kanakkanatt, Mallow and Myerson that would be found in the packages of Wolfbeis and because of the ability to prevent the dye(s) from leaching as taught by Myerson. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a series of indicator compositions as taught by Balderson in the Wolfbeis device because of the ability to provide information on relative changes in the packaged environment and overcome problems with prior art devices as taught by Balderson.

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6. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The change in the claims prompted the reexamination of the Myerson reference and the realization that it in fact taught the instantly claimed acid catalyzed polymerization of the required monomers to form a sol-gel as required by the claims and taught in the instant specification (see the examples). One of skill in the art would also have recognized that the leaching problem as taught by Myerson would have been overcome in the Wolfbeis device by the incorporation of the Myerson sol-gel combination.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose current telephone number is (571) 272-1265 as a result of the examiner moving to the new USPTO location. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


December 7, 2004

ARLEN SODERQUIST
PRIMARY EXAMINER